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Improving Treatment and Prevention of Travelers' Diarrhea Among Deployed Personnel

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Story courtesy of Naval Medical Research Center Public Affairs

Recently Cmdr. Ramiro Gutierrez, from the Naval Medical Research Center's (NMRC) Enteric Diseases Department (EDD) spent two weeks in Soto Cano Air Base, Honduras, as a site investigator supporting field trials aimed at improving the treatment and prevention of travelers' diarrhea (TD) among deployed personnel.

"Joint Task Force-Bravo, located at Soto Cano Air Base in Honduras operates air and other operations maintaining a forward presence in order to enhance regional security, stability and cooperation," said Gutierrez. "Over the last year, Soto Cano was activated as the fourth site to take part in an antibiotic treatment study. TrEAT TD is a randomized double-blind field trial aimed at determining optimal single-dose therapies for active duty personnel with travelers' diarrhea. The study is led by Cmdr. Mark Riddle, also from EDD."

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For this study researchers are evaluating single dose regimens to be used to treat febrile diarrhea/dysentery or acute watery diarrhea. For watery diarrhea the three regimens include azithromycin, levofloxacin or rifaximin (all with loperamide). For fever/dysentery the regimens are azithromycin with or without loperamide.

British Army Training Unit Kenya, Africa; Camp Bastion-Afghanistan, and Camp Lemonnier, Djibouti are the other field trials sites.

While in Honduras, Gutierrez enrolled, treated and followed study subjects in the TrEAT TD study. Gutierrez is also the principal investigator for another research project called Prevent TD, a multi-site, randomized, placebo-controlled, diarrhea field trial, which will evaluate the non-absorbable antibiotic rifaximin as chemoprophylaxis for travelers' diarrhea. While in Honduras he met with base leadership, other personnel and potential participants in both studies.

Until a vaccine is available, other strategies need further evaluation to include chemoprophylactic strategies.

In January, Gutierrez and an Infectious Diseases Clinical Research Program (IDCRP) team of investigators conducted meetings with their British Army Medical counterparts in London to plan future collaborations such as Prevent TD.

According to Gutierrez, despite sanitation and other measures, deployed personnel suffer high rates of travelers' diarrhea. The incidence appears to be highest during operationally dynamic periods and has continued to result in significant rates of disease during recent military operations abroad.

Progress in the development of a vaccine which targets the most common travelers' diarrhea

pathogens (diarrheagenic E.coli, Campylobacter and Shigella) remains a priority and continues to be a focus of NMRC and Walter Reed Army Institute of Research (WRAIR) enteric research efforts; a final product with the required valency and efficacy characteristics remains years away. Until a vaccine is available, other strategies need further evaluation to include chemoprophylactic strategies.

The follow-on trial to TrEAT TD, Prevent TD, will test the protective efficacy of the non-absorbable antibiotic, rifaximin, against travelers' diarrhea for active duty personnel on short deployments. Prevent TD, like TrEAT TD, will include both U.S. and British personnel located at multiple deployment locations but will focus on British troops on training in Kenya and U.S. personnel deployed to Asia and Soto Cano AB Honduras.

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Navy Researchers continue overseas collaborations at deployment sites in Kenya and Honduras. Prevent TD will also be the first trial to take advantage of the IDCRPs TravMIL trial framework on which to overlay the trial procedures. The IDCRPs TravMIL protocol currently enrolls active duty personnel prior to deployment and uses stool and serum sampling, and volunteer diaries to collect exposure data to pathogens and other health threats while on travel.

Prevent TD will overlay a randomization step and rifaximin vs. placebo administration during the pre-deployment visit, and utilize the TravMIL protocol to obtain endpoint data for the efficacy determination. In the future, the TravMIL structure will continue to be used to evaluate a host of other prophylactic measures against travelers' diarrhea or other threats.

"At this time there is a lack of military specific treatment and prophylaxis guidance against travelers' diarrhea, and there is much variability in practice patterns among military medical providers," said Gutierrez. "The goal of Prevent TD and TrEAT TD is to provide evidence from controlled, randomized trials from which to base military specific guidance."

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infected report decrease in job performance and one in ten will go on to develop post-infectious irritable bowel syndrome.

Next summer, after the completion and initial review of results from TrEAT TD, the information will become available and a U.K.-U.S. treatment conference will be assembled to discuss and generate the first evidence-based treatment guidelines for military management of travelers' diarrhea.

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The Enteric Diseases Department's research program is centered on the development of effective countermeasures to prevent or abate bacterial diarrhea, with most efforts aimed at vaccine research and development.

The Enteric Diseases Department is organized into four closely integrated branches: Molecular Biology, Immunology, Biochemistry, and Clinical Trials. Principal investigators work with a number of extramural academic, industry and government partners to achieve the goal of developing new-generation vaccines against travelers' diarrhea.

In the realm of clinical trials, the WRAIR/NMRC facilities afford access to the WRAIR Pilot Bioproduction Facility for scale-up and manufacture of investigational vaccines and with a state of- the-art outpatient clinical trials center where Phase I safety and immunogenicity trials are conducted.

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